

(f)(1) The decision of a hearing before a Public Board of Inquiry or a public advisory committee under this section has legal status of and will be handled as an initial decision under § 12.120.

(2) The decision of a public hearing before the Commissioner under this section will be issued as a final order. The final order will have the same content as an initial decision, as specified in § 12.120 (b) and (c).

(3) Thereafter, the participants in the proceeding may pursue the administrative and court remedies specified in §§ 12.120 through 12.159.

(g) If a hearing before a public advisory committee or a hearing before the Commissioner is used as an alternative form of hearing, all submissions will be made to the Dockets Management Branch, and § 10.20(j) governs their availability for public examination and copying.

(h) This section does not affect the right to an opportunity for a hearing before a public advisory committee under section 515(g)(2) of the act regarding device premarket approval applications and product development protocols. Advisory committee hearing procedures are found in part 14.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commissioner will publish a notice setting forth the following:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The parties to the hearing.

(4) The issues of fact on which a hearing has been justified.

(5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 12.28.

(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 12.45.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The prehearing conference may not commence until after the time expires for filing the notice of participation required by § 12.45(a).

(9) The time within which participants should submit written information and views under § 12.85. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing. The portions listed will be placed on public display in the office of the Dockets Management Branch before the notice is published. Additional copies of material already submitted under § 12.85 need not be included with any later submissions.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the issues to include an issue on which the Commissioner has not granted a hearing or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation under § 12.20(e), the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commissioner shall publish a confirmation of the effective date of the regulation. The FEDERAL REGISTER document confirming the effective date of the regulation may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA,